UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,925	06/20/2001	Seiichi Araki	MTSU-1001US	7925

21302 7590 04/21/2005

KNOBLE, YOSHIDA & DUNLEAVY
EIGHT PENN CENTER
SUITE 1350, 1628 JOHN F KENNEDY BLVD
PHILADELPHIA, PA 19103

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

IV

Office Action Summary	Application No.	Applicant(s)	
	09/806,925	ARAKI ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *153-204* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *153-204* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

MC

DETAILED ACTION

Applicant's amendment and response filed January 25, 2005 has been received and entered into the case. Claims 153 – 204 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:.

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 153 – 204 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the phrase "including one or more non-saccharides" is not described in the specification as originally filed. While the specification does disclose fractions of sugar cane that contain sucrose, and a fraction with "less sucrose", the specification fails to describe a fraction that included "one or more non-saccharides". In addition, as further addressed below, it is unclear what applicant intends this phrase to mean, since the phrase is not defined in the specification. This is a new matter rejection.

3. Claims 153 – 204 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating infection caused by E. coli and pseudorabies, does not reasonably provide enablement for a method for treating any disease caused by any bacteria, fungus or virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The level of predictability in treating infectious diseases is low, particularly regarding bacterial and viral infections such as anthrax, hepatitis, influenza, Ebola and HIV. While a composition may be effective to treat one viral, fungal or bacterial infection, it would certainly not indicate that the same composition would also be effective to treat any other infection. A person of ordinary skill in the art would not immediately recognize that administration of the instant composition would even have a chance of treating any bacterial, fungal or viral infection, simply because a single bacterial and viral infection is treatable with the same composition. The specification fails to set forth any direction or guidance as to how one in the art would go about determining which infections are treatable or even how one would be treated. It would place and an undue burden of experimentation on a person in the art to find suitable infections that could be treated, as well as protocols for treatments therefor.

Applicant argues that while predictability is low, the invention is to control immunological function, not to control a specific antibody as when treating a specific disease, thus one in the art would expect the composition to be effective in all infections. Applicant points to the specification for support in that the composition of the invention will remedy any

infection. Finally applicant cites references to support the assertion that the composition stimulates immunological function.

However, these arguments fail to persuade for the reasons that follow. It is first noted that applicant agrees that the art is unpredictable relative to treating infections caused by bacteria, fungus and viruses. Regarding applicant's assertion that the invention is to control immunological function, the claims are not drawn to a method for controlling immunological function, but are drawn to a method for providing a remedial effect for any disease caused by any bacteria, fungus or virus. Thus the argument is not commensurate in scope with the claims. Furthermore, it is reiterated that the specification provides only two examples for two very specific bacterial infections wherein mice are treated. These examples are certainly not representative of all bacterial infections, let alone fungal and viral infections. Therefore, one in the art would not expect a single composition to provide remedial effects for all bacterial, fungal and/or viral infections in all humans and animals based on these two examples.

Regarding applicant's assertion that the specification states the composition of the invention will remedy any infection, this is not evidence that such an effect will occur. Merely stating that the method can be practiced to remedy any bacterial, fungal or viral infection does not enable one in the art to make and use the composition to practice the claimed invention without undue experimentation. The specification fails to provide adequate guidance to one in the art for practicing the claimed invention relative to any bacterial, fungal or viral infection.

Finally, regarding the references cited by applicant, it is noted that each of these references are a later dated publication than the filing of the instant application. The specification must be enabling as of the filing date. Applicant cannot supplement an insufficient

disclosure with a later dated publication (MPEP 2164.05(a)). Even still, the cited references relied upon further applicant's arguments, in that the composition has immunologically stimulating effects and that the method is intended to control immunological function. However, as already stated, the claims are drawn to a method for providing remedial effects to a disease caused by bacterial, fungal, viral infections. The specification fails to enable one in the art to practice the claimed invention of remedying any disease caused by any bacteria, fungus or virus, as discussed above.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 153 – 204 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 153, 168, 183 and their dependents are drawn to a method of treating however are rendered vague and indefinite for reciting "providing a remedial effect for a disease" because the phrase is not adequately defined by the claim language or specification. It is unclear what applicant intends to include and/or exclude from the scope of the method, since it is unclear what constitutes a "remedial effect".

Applicant argues that symptoms of diseases vary from infection to infection and that one in the art would know what a remedial effect would be relative to each disease.

However, this argument fails to persuade because the specification fails to define if a "remedial effect" must mean the symptoms are cured, or that any improvement of any symptom is achieved. Thus it is unclear what effect must occur to meet the limitation of the claim.

Claims 153, 168, 183 and their dependents are further rendered vague and indefinite for reciting "including one or more non-saccharides" because the claim language and specification fail to adequately define what this limitation intends to encompass. The phrase "including one or more non-saccharides" does not further define the composition, as it does not define what is actually present in the composition. The limitation does not exclude saccharides from the composition, but merely requires "one or more non-saccharides". Therefore it is unclear what the phrase intends to include and/or exclude from the scope of the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 153, 154, 168, 169 and 183 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bermedez.

Applicant claims a method for remedying a disease caused by an infection in humans or animals, the method comprising orally administering an effective amount of sugar cane derived extract including one or more non-saccharides, to a human or animal, wherein the infection is

bacterial or fungal. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, administration is via oral, IV, intramuscular, subcutaneous, intra-abdominal, intrarectal, hypoglossal, or instillation routes; with the proviso that when administration is oral the infection is fungal. Applicant finally claims the method wherein the infection is viral and the sugar cane extract has a MW of less than 1000.

Bermudez teaches methods for treating bacterial, fungal and viral infections, the method comprising administering sugar cane extracts containing amino acids (a non-saccharide) (abstract,p.2). The extracts are obtained from sugar cane and are fractionated/purified with column chromatography (p.10), and are administered orally, topically, intrarectally, enterally, IV, intramuscularly and/or inhalation (p.6).

Although Bermudez does not teach the extract has a MW of less than 1000, the method steps are the same, therefore the product also appears to be the same. Therefore the extract of Bermudez must intrinsically have the claimed MW.

The reference anticipates the claimed subject matter.

Applicant argues that Bermudez teaches a composition comprising 90% carbohydrates and/or saccharides and is made by a different method, thus the composition is not the same.

However, the composition of Bermudez includes amino acids, which is one or more non-saccharides. It is noted that the instant claims to not exclude saccharides from being present in the composition. In addition, the rejected claims merely require the sugar cane to be extracted with column chromatography, which is certainly disclosed by Bermudez. Thus the compositions

are made using the same process. As such, the reference composition does not appear to be structurally different from the instantly claimed composition. Therefore, the claims stand rejected.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 153 – 204 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bermudez, Kawai, Saska, Agar, Brewer and Kearny.

Applicant claims a method for remedying a disease caused by an infection in humans or animals, the method comprising orally administering an effective amount of sugar cane derived

extract including one or more non-saccharides to a human or animal, wherein the infection is bacterial, fungal, or viral. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, administration is via oral, IV, intramuscular, subcutaneous, intra-abdominal, intrarectal, hypoglossal, or instillation routes; with the proviso that when administration is oral the infection is fungal. Alternatively, the extract is obtained by passing sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. The extract is a fraction which absorbs light at a wavelength of 420 nm, separated from other fractions obtained by column chromatography using an ion exchange resin, a cation exchange resin, a strongly acidic cation or the sodium or potassium form, or gel resin. The ion exchange is carried out in a pseudo moving bed continuous separation, and the fraction is further treated with electrodialysis. The extract is obtained by extracting bagasse with water, hydrophilic solvent or mixtures thereof wherein the solvent is ethanol, or a mixture of ethanol and water at 60% or less ethanol, and 40% or more water. Finally, the extract is administered as food or animal feed. Applicant finally claims the method wherein the infection is viral and the sugar cane extract has a MW of less than 1000.

Bermudez teaches methods for treating bacterial, fungal and viral infections, the method comprising administering effective amounts of sugar cane extracts with amino acids (non-saccharide) (abstract, p.2,4). The extracts are obtained from sugar cane and are fractionated/purified with column chromatography (p.10), and are administered orally, topically, intrarectally, enterally, IV, intramuscularly and/or inhalation (p.6). Bermudez teaches the

fractionation and purification can be accomplished by known methods in the art, including chromatography, ion exchange, lipophilic or hydrophobic resins. Bermudez further teaches that the fractions are typically analyzed for their physical-chemical nature, to include MS, laser desorption, infrared, ultraviolet, visible spectrometry and high-resolution nuclear magnetic resonance spectrometry (p.10). Although Bermudez does not teach the extract has a MW of less than 1000, the method steps are the same, therefore the product also appears to be the same. Therefore the extract of Bermudez must intrinsically have the claimed MW.

Bermudez does not teach each of the claimed limitations drawn to the specifics of the fractionation, purification and analysis. However, Bermudez clearly teaches that known methods in the art are used. At the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to obtain the sugar cane extracts of Bermudez via the claimed methods, because they were routinely practiced in the art. In support, Kawai teaches methods for extracting sugar cane wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted with water, methanol, ethanol or mixes thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). In addition, Saska teaches processes wherein sugar juice, or sugar derived molasses is treated with a strong cation exchange resin, in the form or sodium and/or potassium (abstract) and the eluted with water (col.2 line 21-29). Agar teaches methods for pulping plant materials

such as bagasse (sugar cane extract), wherein extracts are recovered by treating the material with organic solvents (alcohol) (col.1 line 21-34, col.16 line 15-20), specifically with 60% ethanol and 40% water (col.4 line 24-26,35-50). Brewer teaches known methods for producing extracts of sugarcane using ion exchange, strongly acidic ion exchange resins (col.2 line 12-22), cations resins of the sodium form (col.2 line 33-39), and electrodialysis (col.3 line 8-10). Finally, Kearney teaches typical separation techniques of sugar extracts include ion exchange resins, continuous simulated moving bed systems (col.1 line 30-50). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practices to obtain the sugarcane extract of Bermudez as claimed, since they well known procedures, as evidenced by the cited references.

It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper (MPEP 2113). Although the instant claims are drawn to a method, the method merely comprises administering such a product by process.

It is further noted that the instant claims read on eating sugar, since the extracts are obtained by the same methods practiced to obtain sugar (see cited references) and the methods are preventative in nature.

Applicant argues that the active agents of Bermudez are not the same as applicants because Bermudez teaches a composition comprising 90% carbohydrates and/or saccharides and is made by a different method, thus the composition is not the same. Applicant further argues that the supporting references teach manufacturing processes, not to modify the composition of Bermudez. Finally, applicant asserts that the method does not read on eating sugar, since the method administers a sugar cane derived extract, not sugar.

However, these arguments fail to persuade because the composition of Bermudez includes amino acids, which is one or more non-saccharides. It is noted that the instant claims to not exclude saccharides from being present in the composition. In addition, the rejected claims merely require the sugar cane to be extracted with column chromatography, which is certainly disclosed by Bermudez. Thus the compositions are made using the same process. As such, the reference composition does not appear to be structurally different from the instantly claimed composition.

Regarding the supporting references, each of the cited references teach various processes for extracting sugar cane which are all well known in the art. Bermudez teaches that any normal method for processing sugar cane can be used in the making of the effective composition. Thus, one of ordinary skill in the art would certainly have been motivated by Bermudez to process sugar cane in the claimed methods, since they were well know and practiced methods as evidenced by the cited supporting references.

Finally, regarding applicant assertion that the claims do not read on eating sugar, it is noted that sugar is, in fact, a sugar can derived extract. Thus, in its broadest, reasonable, interpretation, a sugar cane derived extract certainly includes sugar.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
April 18, 2005
AU 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER